

## REMARKS

The Office Action dated May 7, 2004 has been carefully reviewed. Claims 21-44 are pending in this patent application. By this amendment, claims 22, 30, and 40 have been canceled, claims 21, 26, 34, and 39 have been amended, and claims 45-47 have been added. Reconsideration of this application, as amended, is respectfully requested.

### 35 U.S.C. § 102 Rejection

Claims 21-44 were rejected under 35 U.S.C. § 102 as being anticipated by LaSalle et al. (U.S. Patent No. 5,976,147). Claims 21, 26, 34, and 39 were amended to more clearly define the invention. And claims 22, 30, and 40 were canceled. Reconsideration of claims 21, 23-29, 31-39, and 41-44 is respectfully requested.

### Discussion Re: Patentability of Claim 21

#### *Applicants' Amended Claim 21*

Amended claim 21 reads as follows:

21. A prosthesis evaluation assembly, comprising:  
a tray configured to be supported on a proximal end of a resected tibia, said tray having an opening defined therein; and  
*an evaluation member having (i) a lower portion located within said opening and contacting said tray when said evaluation member is supported on said tray, and (ii) an upper portion configured to support a trial insert thereon, said evaluation member preventing advancement of a tool through said opening of said tray when said lower portion of said evaluation member is received within said opening; and*  
a tool guide having a bore defined therein, said bore of said tool guide being aligned with said opening of said tray so that a tool may be advanced through said bore of said tool guide and said opening of said tray to cut a hole in said proximal end of said resected tibia when said evaluation member is spaced apart from said tray. (Emphasis added.)

LaSalle teaches a bone preparation and trial system. However, LaSalle's system does not disclose an evaluation member that cooperates with the tray as particularly claimed in claim 21. For instance, while LaSalle's tray 12 does have an opening defined therein (see, e.g., guide aperture 30 of Fig. 3), LaSalle does not disclose "an evaluation member having (i) a lower portion located within said opening and contacting said tray when said evaluation member is supported on said tray" as required by amended claim 21. Indeed, the lower portion of LaSalle's elements 16, 18 (alleged by Examiner to equate with the claimed evaluation member) are positioned deep in the tibia when the elements 16, 18 are supported on the tray 12. Note that this is an important distinction since Applicants' invention allows a surgeon to assess stability and kinematics of an implant with a trial insert *before* a hole is drilled in the patient's tibia. On the other hand, LaSalle requires drilling of the hole in the patient's tibia prior to checking stability and kinematics of an implant with a trial insert. Significantly, in order to introduce the punch bushing 16 (see Fig. 1) into the patient's tibia, a hole must be first drilled. (See LaSalle at column 7, lines 33-38.) Applicant's invention enables more accurate alignment of the drilled hole in the tibia in comparison to prior art systems, such as disclosed in LaSalle, because stability and kinematics are able to be assessed prior to drilling the hole.

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since LaSalle does not disclose each and every element of Applicants' amended claim 21, LaSalle does not anticipate Applicants' amended claim 21.

#### Discussion Re: Patentability of Claims 23-25 and 44

Each of claims 23-25 and 44 depends directly from claim 21. As a result, each of claims 23-25 and 44 is allowable over LaSalle for, at least, the reasons hereinbefore discussed with regard to claim 21.

#### Discussion Re: Patentability of Claim 26

Amended claim 26 recites, among other things, the following:

an evaluation member having (i) a tray contact portion located within said opening when said tray contact portion is positioned in contact with a portion of said tray that surrounds said opening defined in said tray, ... , and further no portion of said evaluation member is positioned vertically below said opening defined in said tray when said tray contact portion is positioned in contact with said portion of said tray that surrounds said opening defined in said tray;

In contrast, even if LaSalle's elements 16, 18 (i.e. punch bushing and tibial punch) were construed to be an evaluation member, significant portions thereof are positioned vertically below the opening 30 defined in the tray 12 when the elements 16, 18 are positioned in contact with the tray 12. (See LaSalle at Fig. 2.)

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since LaSalle does not disclose each and every element of Applicants' amended claim 26, LaSalle does not anticipate Applicants' amended claim 26.

#### Discussion Re: Patentability of Claims 27-29 and 31-33

Each of claims 27-29 and 31-33 depends directly or indirectly from claim 26. As a result, each of claims 27-29 and 31-33 is allowable over LaSalle for, at least, the reasons hereinbefore discussed with regard to claim 26.

#### Discussion Re: Patentability of Claim 34

Amended claim 34 recites, among other things, the following:

(e) manipulating said tibia so as to determine stability and kinematics of said trial insert after step (d) and while said lower end of said evaluation member is located within said opening defined in said trial tray;

On the other hand, even if LaSalle's elements 16, 18 (i.e. punch bushing and tibial punch) were construed to be an evaluation member, LaSalle does not teach "manipulating said tibia so as to determine stability and kinematics of said trial insert ... while said lower end of said evaluation member is located within said opening defined in said trial tray" as required by Applicants' claim 34. In contrast, the lower end of elements 16, 18 are positioned deep within the hole previously drilled in the patient's tibia as shown in LaSalle's Fig. 2. (See also LaSalle at column 7, lines 43-54.)

It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since LaSalle does not disclose each and every element of Applicants' amended claim 34, LaSalle does not anticipate Applicants' amended claim 34.

#### Discussion Re: Patentability of Claims 35-38

Each of claims 35-38 depends directly from claim 34. As a result, each of claims 35-38 is allowable over LaSalle for, at least, the reasons hereinbefore discussed with regard to claim 34.

#### Discussion Re: Patentability of Claim 39

The discussion relating to the patentability of amended claim 26 is relevant to the patentability of amended claim 39. As a result, amended claim 39 is allowable over LaSalle.

#### Discussion Re: Patentability of Claims 41-43

Each of claims 41-43 depends directly from claim 39. As a result, each of claims 41-43 is allowable over LaSalle for, at least, the reasons hereinbefore discussed with regard to claim 39.

#### **Newly Added Claims 45-47**

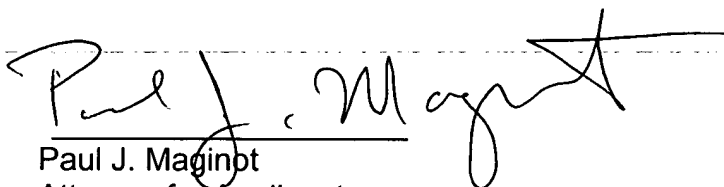
Newly added claims 45-47 recite novel and nonobvious limitations. Thus, each of claims 45-47 is allowable over the cited art.

## Conclusion

In view of the foregoing amendments and remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited.

Respectfully submitted,

MAGINOT, MOORE & BECK

A handwritten signature in black ink, appearing to read "Paul J. Maginot", with a long horizontal stroke extending to the right.

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